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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/647,488 | 08/25/2003 | Kai-yu Tong | MCHK/131/US | 2363 |

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| EXAMINER | |
|---|---|
| BOCKELMAN, MARK | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/647,488 | TONG, KAI-YU | |
| | Examiner | Art Unit | |
| | Mark W. Bockelman | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-14-2007 has been entered.

### *Specification*

The abstract of the disclosure is objected to because of the following errors:

On page 6, line 12 and page 7, lines 12, 13, 17, 18, 19, 20 and 22, the terms "simulate," "simulation" and "simulating" should be changed to "stimulate," "stimulation" and "stimulating," respectively.

On page 11, lines 10-11, it is unclear what type of patient's physical information "ROM" is.

On page 12, line 17, the phrase "includes a patient" should be changed to "include a patient's."

Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haugland et al., US 2003/0144710 (alone) or in view of Nelson et al., USPN 5586557.

Haugland teaches a heel switch placed under the heel of a user for generating a stimulation signal when the foot is lifted during gait (Fig. 5, para. 60), an electrode adapted to contact the user's leg (Fig. 5, paras. 60-65), and a controller coupled to the heel switch and electrode for outputting a stimulation signal to the electrode (Fig. 5, paras. 78-80). Applicant's specification fails to explain the significance and differences between the four portions of the stimulation signal (i.e. rise, stimulation, extension, and fall portions) other than merely being depicted in Fig. 4. To the extent that it is

understood what the different portions are, Haugland is interpreted as disclosing a stimulation signal having a rise portion, a stimulation portion, an extension portion and a fall portion (paras. 90-91). Haugland's controller is also programmed to record a duration of use (50 seconds) and number of steps during that time (Fig. 13, paras. 112, 114, 135 and esp. paras. 131-132). Based on the foregoing, Haugland is interpreted to anticipate claim 1.

Alternatively, Nelson also teaches calculating a duration of use and a number of steps taken over that duration (column 3, lines 15-17). Since Nelson is directed to a device for analyzing and monitoring ambulation during rehabilitation (column 1, lines 11-15), it would have been obvious to incorporate recording the number of steps taken during gait as taught in Nelson into the device of Haugland to more effectively monitor a patient's recovery status during rehabilitation.

Claims 2 and 4-6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland in view of Nelson as applied to claim 1 above, and further in view of Smith et al., USPN 5485402.

As discussed above, Haugland teaches a heel switch placed under the heel of a user for generating a stimulation signal when the foot is lifted during gait (Fig. 5, para. 60), an electrode adapted to contact the user's leg (Fig. 5, paras. 60-65), and a controller coupled to the heel switch and electrode for outputting a stimulation signal to the electrode (Fig. 5, paras. 78-80). The controller is contained in a housing which also includes a receiver for receiving wireless signals from a remote unit (paras. 80, 85), and

stores stimulation data (para. 80). The remote unit may be a hand-held computer that is removably coupled to the controller (para. 85). Again, Haugland is interpreted as disclosing a stimulation signal having a rise portion, a stimulation portion, an extension portion and a fall portion (paras. 90-91). Similarly, Applicant's specification fails to discuss the stimulation data as including a stimulation level, a rise time, a stimulation time, a stimulation time, an extension time, a fall time, a pulse form, a triggering period, a triggering method and a triggering criteria. To the extent that these features are understood, they are considered to be inherently present in Haugland (paras. 73, 79-80, 85-92, 95, 114, 129-133).

While Nelson teaches measuring a duration of use and number of steps taken during that duration, Nelson does not teach recording the number of steps taken in a predetermined duration such as an hour, a day, or a period of dates. Smith on the other hand, discloses storing a number of steps taken during a selected time interval, including hourly or daily (column 4, line 52 - column 5, line 25, Figs. 4-5). Like Nelson, Smith is also directed to a gait activity monitor which may be used for patient rehabilitation. Therefore, it would have been obvious to one of ordinary skill in the art to specify a time interval and count and store the number of steps taken during that interval as taught by Smith, while rehabilitating a patient using the device taught by Haugland modified by Nelson, to provide a more effective means of monitoring a patient's progress during rehabilitation.

Claims 7-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland in view of Nelson and Smith as applied to claims 2, 4-6 and 9 above, and further in view of Sieracki et al, US 2004/0143302.

Haugland, Nelson and Smith disclose each feature of the claimed invention, as discussed above, except for the limitation that the computer may be a Personal Digital Assistant and uses Windows as the graphic user interface. Both of these features are well known. For example, there are several well known types of computers, including desktops, laptops, and PDAs. Moreover, many of these types of computers and other electronic devices (eg cell phones) also use Windows. Sieracki is one example of a programmable therapeutic stimulating device which uses a PDA as the external controller (Fig. 1). It would have been obvious to one of ordinary skill in the art to use a PDA as the computer and/or to use Windows in the computer of Haugland as these are standard options for any application requiring a computer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

June 24, 2007

MARK BOCKELMAN
PRIMARY EXAMINER